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DEPARTMENT OF HEALTH AND HUMAN SERVICE

Public Health Service

Food and Drug Administration
New Orleans District
Southeast Region
4298 Elysian Fields Ave.
New Orleans, LA 70122

Telephone: 504-589-6341
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December 15, 1998

WARNING LETTER NO. 99-NOL-07

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. James A. Rich, Owner/President
Catfish Wholesale, Inc.
Post Office Box 759
Abbeville, LA 70511-0759

Dear Mr. Rich:

During the inspections of Catfish Wholesale, Inc., located at 14013 Louisiana Highway 696, Kaplan, Louisiana 70548, conducted on August 25-28, 1998 and October 6-9 and 19, 1998, our investigators documented numerous insanitary conditions in your picked crabmeat operation. This causes your finished product, picked crabmeat, to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug and Cosmetic Act.

Objectionable conditions noted during the October 1998 inspection included:

1. For each cook observed, raw/live crabs contained in four separate cooking baskets were not completely submerged in the boiling water for the full 20 minute cook cycle;

2. Cooked crabs directly contacted surfaces that had been in direct contact with raw crabs;

3. Raw crab effluent in the cooked crab section of the processing operations splashed on cooked products and on food contact surfaces;

4. Condensate developed on insanitary surfaces and dripped directly on cooked crab products and food contact surfaces;

5. Cooked crab product came in direct contact with employee's insanitary gloves and non-food contact surfaces;

6. Cooked crabs repeatedly contacted areas of picking tables and workstation dividers that were pitted and residue encrusted;

7. Several structural defects created pest entry points, such as holes in the screen around conduit pipes and cracks along the bottom and side of the west wall mounted air conditioner;

8. Flies were observed inside both the cooking (four) and picking (two) rooms during processing operations;

9. Numerous poor employee practices, such as:

    a. picking employees repeatedly handled residue encrusted black water hose nozzles then resumed picking crabmeat without first washing and sanitizing their hands
    b. picking employees used residue encrusted ornate or plastic handled knives to pick crabmeat

10. Unlabeled and toxic substances were present in the picking and packing rooms during processing.

Similar objectionable insanitary conditions were noted during the August 1998 inspection. The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with each requirement of the Good Manufacturing Practice Regulations.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. This may include seizure and/or injunction.

You should notify this office in writing, within 15 working days of receipt of this letter, of the steps taken to correct the above noted violations, including an explanation of each step taken to prevent the recurrence of similar violations. If corrective action can not be completed within 15 working days, state the reason for this delay and the time within which the corrections will be completed.

Additionally, the August 1998 inspection was conducted to determine compliance with FDA's seafood processing regulations (21CFR123).

The seafood processing regulations, which became effective on December 18, 1997, require you to implement a preventive system of food safety controls known as Hazard Analysis Critical Control Point (HACCP). HACCP essentially involves: (1) identifying food safety hazards that, in the absence of controls, are reasonably likely to occur in your products; and (2) having controls at "critical control points" in the processing operations to eliminate or minimize the likelihood the identified hazards will occur. These are the kinds of measures prudent processors already take. HACCP provides a systematic way of taking those measures that demonstrates to us, to your customers, and to consumers, that you are routinely practicing food safety by design. Seafood processors that have fully operating HACCP systems advise us that they benefit from it in several ways, including having a more safety oriented workforce, having less product waste, and having fewer problems generally.

During the inspection of your fresh picked crabmeat, vacuum packed frozen crabmeat and frozen packed crawfish tail meat operations, the FDA investigator observed shortcomings in your system that, upon preliminary review, appear to be deviations from the principles of HACCP and the significant

requirements of the program. The FDA investigator also provided you with a copy of the Domestic Seafood HACCP Report (form FDA-3501) and the FDA-483, which presents his/her evaluation of your firm's performance regarding various aspects of the HACCP and GMP requirements. The observations of concern to us are as follows:

Regarding your firm's HACCP plan for fresh picked crabmeat operations:

- Failure to establish a HACCP plan to address the hazard(s) associated with fresh picked crabmeat;
- Failure to adequately monitor the following sanitation elements: conditions and cleanliness of food contact surfaces, prevention of cross contamination, protection from adulterants, and exclusion of pests;
- Failure to include prevention of cross contamination and protection from adulterants as sanitation elements in the sanitation monitoring records; and,
- Failure to document insanitary conditions or their corrections in your firm's sanitation monitoring records for the following sanitation items on August 25-26, 1998: conditions and cleanliness of food contact surfaces, protection from adulterants and exclusion of pests.

Regarding your firm's HACCP plan for vacuum packed frozen crabmeat operations:

- Failure of your firm's HACCP plan to include the firm address, the species (identity) of the fishery component, description of the finished product, packaging type, method of distribution, and intended use and customer;
- Failure of your firm's HACCP plan to address the hazard(s) associated with vacuum packed frozen crabmeat after cooking and before vacuum packing; and,
- Failure to include prevention of cross contamination and protection from adulterants as sanitation elements in the sanitation monitoring records.

Regarding your firm's HACCP plan for frozen vacuum packed crawfish tail meat operations:

- Failure of your firm's HACCP plan to include the firm address, the species (identity) of the fishery component, description of the finished product, packaging type, method of distribution, and intended use and customer;
- Failure of your firm's HACCP plan to address the hazard(s) associated with vacuum packed frozen crawfish after cooking and before vacuum packing; and,
- Failure to include prevention of cross contamination and protection from adulterants as sanitation elements in the sanitation monitoring records.

Regarding your firm's sanitation monitoring records for fresh and frozen catfish operations:

- Failure to include prevention of cross contamination and protection from adulterants as sanitation elements in the sanitation monitoring records, and

- Failure to document the insanitary condition, exclusion of pests, or its correction in your firm's sanitation monitoring records for August 25, 1998.

Objectionable equipment and insanitary conditions as listed on Form FDA-483 and Form FDA-3501 are an indication that sanitation monitoring [21 CFR 123.11(b)] at the firm is inadequate. Calling your attention to the objectionable insanitary conditions in this letter is in the interest of having your firm improve its sanitation program consistent with the HACCP principles. A failure to make appropriate corrections could cause your HACCP processing system to be found unacceptable during a future FDA inspection. The noted objectionable insanitary conditions are listed in paragraph two (2) of this letter.

We encourage you to make the necessary improvements as soon as possible. However, if you disagree with FDA's preliminary assessment of deviations from HACCP Regulations, you should explain how your system identifies hazards and implements controls in a manner the agency should regard as complying with the regulations. We understand that HACCP systems may be uniquely tailored to meet the circumstances of the individual processor and there may be more than one right way to control hazards.

In either case, it is essential that you respond to this office on these HACCP matters within 30 working days of the receipt of this letter. Upon receipt of a timely response, we will work with you to resolve any outstanding issues associated with your HACCP system. If we do not hear from you, or if your response is inadequate, we will assume our preliminary conclusions are correct and we will schedule a follow-up inspection for the immediate future.

Your reply, relating to these insanitary and HACCP concerns, should be directed to the Food and Drug Administration, Attention: Nicole F. Hardin, 4298 Elysian Fields Avenue, New Orleans, Louisiana 70122-3896.

If you have questions regarding the implementation of the HACCP regulation or the application of HACCP to your specific process, you may contact Ms. Hardin at (504) 589-7166 for answers and/or direction towards guidance and sources of training in achieving compliance.

Sincerely,

James E. Gamet
District Director
New Orleans District

Enclosures